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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,916	05/09/2006	Peter MacDonald	13150/46201	6750

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EXAMINER	
BASQUILL, SEAN M	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
12/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,916	MACDONALD ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6 Aug 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Previous Rejections

1. Applicants' arguments, filed 9 July 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 5-8, and 10 stand, and Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,794,503 ("La Loggia") for the reasons put forth in the previous action.

Applicants arguments have been fully considered and are deemed unpersuasive. Certainly, in reviewing the applicants disclosure as originally filed, all examples utilize either a phenyl or substituted phenyl moiety as substituent R1. However, the claims as currently presented are not so limited. The examiner must interpret all claims presented as broadly as reasonable in light of the specification (MPEP 2111), giving the words used in a claim their plain meaning unless such meaning is inconsistent with the specification (MPEP 2111.01(I)), but must refrain from importing limitations into the claims from the specification. MPEP 2111.01(II). Instant Claim 1, for example, recites "R1 is phenyl or phenyl substituted with halogen, hydroxy,

amino, mono- or di-C,-C8 alkylamino, Ct-C8 alkyl, CI-C8 alkoxy and/or CI-C8 carbalkoxy," which the examiner maintains should be read as "R1 is phenyl, or phenyl substituted with halogen, ***or*** hydroxy, ***or*** amino, ***or*** mono- ***or*** di-C1-C8 alkylamino, ***or*** C1-C8 alkyl, ***or*** C1-C8 alkoxy ***and/or*** CI-C8 carbalkoxy," rendering the acetoxy groups of La Loggia, MacDonald, and Chernyak anticipatory of the claims as presented. The examiner suggests that, to actually claim an invention more in keeping with the examples presented in the remainder of the disclosure, Claim 1 (and Claims 4, 10 and 11) be amended to read "wherein R1 is phenyl or phenyl substituted ***with a member selected from the group consisting of*** halogen, hydroxy, amino, mono- or di-C,-C8 alkylamino, Ct-C8 alkyl, CI-C8 alkoxy and/or CI-C8 carbalkoxy" to clearly indicate that ONLY phenyl groups bearing such substituents as presented above fall within the scope of the invention as claimed. To further assist applicants in advancing prosecution, the examiner strongly suggests amending the claims to exclude unsubstituted phenyl groups from the scope of the invention as claimed (so that for example Claim 1 would read "wherein R1 is phenyl substituted ***with a member selected from the group consisting of*** halogen, hydroxy, amino, mono- or di-C,-C8 alkylamino, Ct-C8 alkyl, CI-C8 alkoxy and/or CI-C8 carbalkoxy"), as benzoyl groups are well-known and commonly-used hydroxyl moiety protecting groups in steroid synthesis. *See* Sharmilla Banerjee, *et al*, *On The Protection of 3a-Hydroxy Group of A/B cis Steroids*, 21 SYNTH. COMM. 757 (1991).

3. Claim 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,255,331 ("MacDonald") for the reasons put forth in the previous action.

Applicants arguments have been fully considered and are deemed unpersuasive for the reasons put forth in the discussion of the La Loggia rejection, above.

4. Claims 1-3 and 5-10 stand rejected under 35 U.S.C. 102(e) as being anticipated by International Patent Application Publication WO03/047329 ("Chernyak") for the reasons put forth in the previous action.

Applicants arguments have been fully considered and are deemed unpersuasive for the reasons put forth in the discussion of the La Loggia rejection, above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 5-10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chernyak as described above.

Chernyak describes the synthesis of 6-fluoro pregnanes, as detailed above, but does not specify the use of an amine salt in amounts of between 50-90% by weight of the starting materials.

However, Chernyak does indicate that salts of catalysts such as, for example p-toluenesulfonic acid or methanesulfonic acid (Pg. 9), may be formed by their neutralization with bases such as triethylamine. (Pg.14-15). Chernyak indicates that such acids act as catalysts, and the presence of additional catalyst enables reactions to proceed more rapidly. The amount of catalyst present is a result effective variable which may be optimized by the routine experimentation of the artisan possessing ordinary skill. MPEP 2144.05(II). Therefore, adjusting the amount of catalyst used to fall within the range claimed by the applicants is *prima facie* obvious.

6. Claims 1-3, 5-8, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over La Loggia as applied to claims 1-3, 5-8, 10, and 11 above, and further in view of U.S. Patent 2,961,441 (hereinafter "Bogert").

La Loggia describes the preparation of 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate by reaction of 15g 9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione with isopropyl acetate and 0.6g p-toluenesulfonic acid to form the di-acetate, the reaction which was then quenched with 0.48ml triethylamine and acetonitrile. (C.5, L.35-50). In additional embodiments, the acid used is methanesulfonic acid which is then buffered with triethylamine. (C.7, L.29-32). Additional acetonitrile was added after evaporation of the previous solution, along with ACCUFLUOR, e.g., 1-Fluoro-4-hydroxy-

1,4-diazoniabicyclo [2.2.2]octanebis(tetrafluoroborate), and the reaction was permitted to continue at 0C for 12 hours. Solid 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate was obtained as a solid which was then cleaned by water and ammonia rinse to yield 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate in a 6a:6B configuration ratio of 93.5:6.5. (C. 5, L.50-60).

La Loggia does not specify the use of a salt such as pyridine methylsulfonate in the formation of 6-fluoro pregnanes.

Bogert indicates that, in reactions which form 6-fluorosteroids, bases such as pyridine and triethylamine are advantageously employed in various schema, conveying their essential exchangeability in such syntheses. (C.2, L.1-14).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have used both methanesulfonic acid and pyridine in reactions directed to forming 6a-fluoro-9B,11B-epoxy-17a-hydroxy-16B-methylpregna-1,4-diene-3,20-dione-21-acetate. One having ordinary skill in the art would have been motivated to do so because La Loggia indicates that methanesulfonic acid can be used in place of p-toluenesulfonic acid, and Bogert describes the essential equivalence of pyridine and triethylamine is such synthetic schema. Generally, it is *prima facie* obvious to select a known material for substitution into a method, based on its recognized suitability for its intended use. MPEP § 2144.07. Because methanesulfonic acid would react with pyridine to form pyridine methylsulfonate, the limitation of instant Claim 12 is met.

Double Patenting

7. Claim 10 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 4,255,331. Applicants arguments have been fully considered and are deemed unpersuasive for the reasons put forth in the discussion of the La Loggia rejection, above.

Conclusion

No Claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1612

/JEFFREY S. LUNDGREN/
Primary Examiner, Art Unit 1639